

GUIDELINES FOR REVIEWER'S WRITTEN COMMENTS NIDDK MENTORED CLINICAL SCIENTIST AWARD (K08)

The K08 award is intended to provide three to five years of research support in the transition between fellowship or trainee experience or clinical training and a career in independent investigation for clinically-trained individuals. Refer to the NIH Guide announcements (PA-00-003, 10/8/99) for more detail about the award. The format outlined below should be followed in preparing your comments for each K08 application assigned to you. Include additional headings when they seem appropriate to the review. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria. Primary and secondary reviewers should address all points outlined below. The written critique for a discussant review may be brief; all aspects of the five review criteria do not need to be specifically addressed. A brief paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques. If you prefer to prepare a full critique equivalent to a primary or secondary review, you also have that option.

RESUME: In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the candidate's research career and how these factors determine your overall merit rating of the application.

Candidate: Describe and evaluate the candidate's qualifications and commitment to a career in biomedical research.

For individuals having little prior research exposure, evaluate his/her quality and extent of past education and clinical training experience. For individuals having more research background, assess his/her quality and extent of past education, scientific training, and clinical research experience; and the quality of any independent research publications. For all candidates, weigh their commitment to a career in health-related research; the need for further training and how the award will contribute to immediate and long-term career objectives; and letters of reference which must address their potential for a research career.

Career Development Plan: Describe and evaluate the career development plan, incorporating consideration of the candidate's goals and prior experience. For individuals with limited or no prior research experience, the didactic component, proposed during the first year or two, must be integrated fully into the training program and justified on the basis of their needs. If course work is proposed for candidates with greater research experience, it must be integrated adequately into the training program.

Research Plan: Assess the research plan outlined, including the specific aims, background and significance, progress report/preliminary studies, and research design and methods for its feasibility, scientific soundness, and potential to achieve the goal of this award. Determine the appropriateness of this project for the candidate at his/her stage of development and as a vehicle to acquire research skills necessary for independence.

Mentor: Evaluate the mentor's research qualifications in the area of the project, extent and quality of his/her proposed role in guiding and advising, previous experience in training researchers, and history of research productivity and support. If more than one mentor is identified, the qualifications, role, and commitment of each must be discussed.

Environment And Institutional Commitment: Evaluate the institution's commitment to the candidate's career development. Indicate the types of facilities, resources, and training opportunities to be made available to the candidate, including the assurance that 75 percent of his/her full-time effort will be protected for this program.

Action: The application may be recommended for no further consideration, deferred in order to obtain

additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

Budget: Comment on the appropriateness and justification of the budget request within the context of the goal of the award. The candidate's salary may not exceed \$75,000. Up to \$25,000 per year is allowed for tuition, fees, and books related to career development; research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time. Justify any proposed changes.

Other Considerations

If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Instruction in the Responsible Conduct of Research: All applicants must receive instruction in the responsible conduct of research, and the proposed subject matter, format, frequency, and duration of instruction must be detailed. This component must be included in the application.

Involvement of Human Subjects: Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children (individuals under 21 years of age) have been included in the research and if their inclusion or exclusion has been justified adequately to justify the code to be assigned. If a data and safety monitoring plan is required, indicate if it is adequate. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications."

Animal Welfare: If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury.

Hazardous Materials and Procedures: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.